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PH. EUR. POLICY ON ELEMENTAL IMPURITIES - CLARIFICATION FOR PRODUCTS OUTSIDE THE SCOPE OF THE ICH Q3D GUIDELINE

The European Pharmacopoeia Commission published its implementation strategy for the ICH Q3D guideline for elemental impurities, in a press release dated 28th April 2015.

Since then, the list of individual monographs affected by the proposed deletion of the cross-reference to wet chemical testing for heavy metals (2.4.8) has been published for public consultation in Pharmeuropa 27.2 (deadline for comment was 30/06/2015). The cross-reference to chapter 2.4.8 would be deleted from all monographs on substances for human use only and for human and veterinary use, but not from monographs on substances for veterinary use only; hence the chapter Heavy Metals (2.4.8) itself would be kept in the Ph. Eur.

As highlighted in the Press release dated 28th April 2015, the European Pharmacopoeia Commission decided to reproduce verbatim the ICH Q3D guideline in the Ph. Eur. chapter 5.20. This decision also concerns the scope of the guideline, and a cross reference to chapter 5.20 in the general monograph Pharmaceutical Preparations (2619) would be made so that the scope within the Ph. Eur. is equivalent to that of the guideline itself.

For products outside the scope of the ICH Q3D guideline such as products for veterinary use, the absence of elemental impurities (incl. heavy metals) tests from an individual monograph on a substance used for their production does not release manufacturers from the need to control the level of such elements in their products, where relevant. Indeed, it is considered the final responsibility of the manufacturers to assess and control, where needed, such impurities in a drug product using the principles of risk management as laid down for example in the ICH Q9 guideline or in the ICH Q3D guideline. Methods provided in the Ph. Eur. (such as the chapters 2.4.8., 2.4.20) could be used for the control of elemental impurities. In those cases, the suitability of the testing procedures will have to be demonstrated by the manufacturer. Finally, the control strategy as well as the demonstration of suitability will be part of the marketing authorisation application dossier and the assessment of these data part of the marketing authorisation procedure.

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Note for the Editor: Further information is available on the internet site **www.edqm.eu**
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[1]There are now thirty-eight members of the European Pharmacopoeia Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, the Former Yugoslav Republic of Macedonia, Turkey, Ukraine, United Kingdom and the European Union. There are twenty-eight observers: Albania, Algeria, Argentina, Armenia, Australia, Azerbaijan, Belarus, Brazil, Canada, China, Georgia, Guinea, Israel, Kazakhstan, Republic of Korea, Madagascar, Malaysia, Republic of Moldova, Morocco, Russian Federation, Senegal, Singapore, South Africa, Syria, Tunisia, United States of America, the Taiwan Food and Drug Administration (TFDA) and the World Health Organization (WHO).*

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